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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,161	08/17/2001	Olivier Civelli	P-UC 4679	5376
23601	7590	06/09/2004		
CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122			EXAMINER DEBERRY, REGINA M	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/932,161	<b>Applicant(s)</b> CIVELLI ET AL.	
	<b>Examiner</b> Regina M. DeBerry	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-14 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) 36-38 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11, 12, 41 and 42 is/are allowed.
- 6) ☒ Claim(s) 2-10, 13, 14, 35, 39, 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Status of Application, Amendments and/or Claims***

The amendment filed 03 March 2004 has been entered in part. Claims 1, 15 and 34 are cancelled. New claims 36-42 were submitted, however, claims 36-38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 36-38 now recite polypeptides comprising SEQ ID NOs. The instant claims would require a species election. Please see Election/Restriction requirement 02 December 2002.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36-38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 2-14, 35, 39-42 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections And/Or Rejections***

The rejection of claims 1, 2, 15 and 34 under 35 USC 112, First Paragraph, Scope of Enablement, as set forth at pages 2-5 of the previous Office Action 03 November 2003, is *withdrawn* in view of the amendment 03 March 2004.

The rejection of claims 1, 15 and 34 under 35 USC 112, First Paragraph, Written Description, as set forth at pages 5-7 of the previous Office Action 03 November 2003, is *withdrawn* in view of the amendment 03 March 2004.

The rejection of claim 2 under 35 USC 112, Second Paragraph, as set forth at page 7 of the previous Office Action 03 November 2003, is *withdrawn* in view of the amendment 03 March 2004.

#### **Claim Rejections - 35 USC § 102(a)**

Claim 35 remains rejected under 35 U.S.C. 102(a) as being anticipated by Zhang *et al.* (Society for Neuroscience Abstracts, 1999). The basis for this rejection is set forth at pages 7-8 of the previous Office Action (03 November 2003).

Applicants maintain that without any indication that either nonREM or REM sleep was reduced by PrRP treatment, the assertion that treated rats are coming out of REM sleep is invalid. Applicants argue that Zhang *et al.* state that nonREM sleep was increased by 27.2%, which does not mean 27.2% reduction in REM sleep. Applicants maintain that Zhang *et al.* describe only increases in sleep, whether nonREM or REM sleep and increasing sleep is the opposite of promoting wakefulness. Applicants submit Exhibit A, which describes sleep stages.

Applicants' arguments have been fully considered but are not deemed persuasive. Exhibit A teaches that nonREM sleep is comprised of stages 1-4, with only stages 3 and 4 being deep sleep (slow wave). The specification

describes "promoting wakefulness" to include a decrease in any stage of sleep, light sleep, deeper sleep characterized by the presence of high amplitude, low wave brain activity termed slow wave sleep and REM (specification, page 15, lines 21-30). The specification also states that a compound that promotes wakefulness can, for example, prolong normal latency to sleep or restore normal sleep patterns following sleep deprivation (specification, page 16, lines 1-6). Thus the specification like the results of Zhang *et al.* are open for different interpretation. At various points in the rat experiments of Zhang *et al.*, both nonREM and REM sleep patterns were being increased.

However and most importantly, the same exact step would equal the same exact effect, it would be inherent that administered PrRP, as taught by Zhang *et al.*, would have the property of promoting wakefulness. The prior art has all of the features required to perform the intended use recited in the instant claims, as there are no distinguishing features between the instant PrRP and the PrRP of Zhang *et al.* A compound and all of its properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). The evidence as a whole indicates that the rejection should be maintained.

#### **Claim Rejections - 35 USC § 103(a)**

Claims 2-10, 13, 14, 39 and 40 remain rejected under 35 U.S.C. 103(a) as being unpatentable over being unpatentable over Zhang *et al.* (Society for Neuroscience Abstracts, 1999) in view of Curran *et al.*, US Patent No. 6,323,177 B1 and Roland *et al.*, Endocrinology, 1999 (IDS submitted by Applicant). The

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basis for this rejection is set forth at pages 8-10 of the previous Office Action (03 November 2003).

Applicants argue that the combination of Zhang *et al.* and Curran *et al.* does not teach or suggest the method of claims 1, 13 and 14. Regarding claims 2-10, Applicants maintain that the the combination of Zhang *et al.* Curran *et al.* and Roland *et al.* does not teach or suggest the claimed methods.

Applicants' arguments have been fully considered but are not deemed persuasive. The key issue at dispute is the Zhang *et al.* reference. The Examiner has discussed the rejection in the maintained 35 USC 102(a) rejection. Curran *et al.* teach the screening of very large libraries for receptor agonists and antagonists. Roland *et al.* teach that PrRP binds the PrRP receptor (GPR10) and stimulates calcium mobilization. Roland *et al.* teach the screening of other PrRP receptor agonists. The evidence as a whole indicates that the rejection should be maintained.

**Conclusion**

Claims 2-10, 13, 14, 35, 39 and 40 are rejected.

Claims 11, 12, 41 and 42 are allowed.

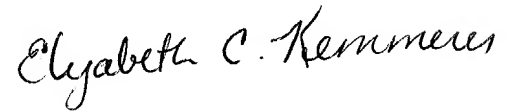
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ELIZABETH KEMMERER  
PRIMARY EXAMINER



RMD

6/7/04